REMARKS

Reconsideration and reexamination of the subject application are respectfully requested in light of the foregoing amendments and following remarks.

Applicant respectfully requests an interview with the Examiner prior to reconsideration and reexamination of the application.

1. Support for the Amendments

The amendments to the claims are supported throughout the specification as filed and do not enter new matter into the application. Claims 3-4 are canceled to expedite prosecution. The claims are canceled without disclaimer and without prejudice to Applicant's rights to obtain protection to the subject matter of any canceled claim in a continuing application. New claims 5 and 6 are supported through out the specification as filed. The Examples, for instance, describe the claimed *in vitro* method and kit components to carry out the claimed method.

The amendment to claim 1 recites that the claimed oligoribonucleotides "target" recited bases of human StAR binding protein gene. Support for target sequences within the SBP gene is found throughout the specification as filed. For example, the specification states at page 11, lines 7-9:

> In [Example 6], SBP expression was suppressed by interference RNA and steroid hormones were examined. Two target sequences in SBP gene [were] selected and the effect of siRNA was measured by RT-PCR.

For this reason, the inventor had possession of the presently claimed subject matter at the time the specification was filed. Claim 2 is presently amended to avoid substantial duplication with amended claim 1.

2. Status of the Claims

Claims 1-4 stand pending. Claims 1-4 stand rejected. Claims 3 and 4 are canceled, and new claims 5 and 6 are added.

3. Acknowledgement of Sequence Compliance

Applicant notes with appreciation the indication that the Examiner has received the Sequence Listing and CRF, and deems them acceptable.

4. Acknowledgement of Oath/Declaration

Applicant notes with appreciation the indication that the Oath/Declaration filed in the instant application complies with 37 C.F.R. § 1.63.

5. Acknowledgement of Information Disclosure Statement

Applicant notes with appreciation the acknowledgement of the Information Disclosure Statement filed February 22, 2007.

6. Priority

The Office indicates that an English translation of the priority document, JP 2003/278429, is not present. The Office accordingly grants the application the benefit of priority to the international filing date, March 13, 2004, from PCT/JP04/03449. To clarify the record, the presence or absence of a translation does not affect Applicant's right to claim priority under 35 U.S.C. § 119(a). Instead, the Manual of Patent Examining Procedure, 8th ed., revised August 2006 (MPEP) § 201.15 indicates that a translation of a foreign priority document is only required if an applicant relies on the priority document to overcome a rejection made by the Office. Unless that circumstance arises, Applicant is under no obligation to provide a translation of JP 2003/278429. In any event, Applicant is entitled to claim priority to the July 23, 2003 filing date of JP 2003/278429 under 35 U.S.C. § 119(a).

7. Rejection of the Claims Under 35 U.S.C. § 112, Second Paragraph

(1) Claims 1-4 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office alleges the claims are unclear, because claims 1 and 2 recite an RNA molecule, whereas the claims also refer to SEQ ID NO: 1, which is a DNA sequence. Applicant traverses the rejection.

It is well established that Applicant can define in the claims what he regards as his invention in whatever terms he chooses so long as any special meaning assigned to a term is clearly set forth in the specification. *See In re Zletz* , 893 F.2d 319, 321-22, 13 U.S.P.Q.2d 1320, 1322 (Fed. Cir. 1989); *see also* MPEP §§ 2111.01, 2173.01. The specification provides at page 4, lines 6-10, that an "oligoribonucleotide" characterized as "substantially identical to" a specific nucleotide sequence, e.g., SEQ ID NO: 1, means that the T in the specified nucleotide sequence is replaced by U in the oligoribonucleotide. Thus, there is no contradiction between the recited oligoribonucleotide and the referenced sequence in SEQ ID NO: 1. The rejection accordingly may be withdrawn.

(2) The Office also rejects claims 1 and 2 because the claims "possibly" may be directed to non-statutory subject matter, if the recited RNAs were found in nature. Office Action, page 3. Without substantive arguments in support of the rejection, the Office has not made a *prima facie* rejection to which Applicants can respond. If the Office maintains this rejection, Applicant urges the Office to clarify the statutory grounds for the rejection, so that Applicant can respond accordingly. In this case, any such amplification of the rejection cannot be made final in the next Office Action.

Moreover, claims 1 and 2 are directed, in part, to an oligoribonucleotide substantially identical to less than 23 contiguous nucleotides of the nucleotide sequence of SEQ ID NO: 1. The presently recited oligoribonucleotide is *smaller than the full length* nucleotide sequence of SEQ ID NO: 1. The recited oligoribonucleotide cannot occur naturally, for example, as an mRNA transcript substantially identical to SEQ ID

NO: 1. Accordingly, the skilled artisan would understand from the claims, when read in light of the specification and the state of the art, that the claimed subject matter is not directed to naturally occurring molecules. Accordingly, the rejection is improper and may be withdrawn.

8. Rejection of the Claims Under 35 U.S.C. § 112, First Paragraph

Claims 3-4 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, "while being enabling for [an] *in vitro* method for inhibiting expression of SBP in cancer cells," allegedly does not enable a method comprising inhibiting expression of SBP *in vivo*. Office Action, page 4. Applicant appreciates the indication of enabled subject matter and respectfully traverses the rejection.

To expedite prosecution, Applicant has amended the claims to recite a method for inhibiting expression of SBP gene in cancer cells, comprising introducing into cancer cells ***in vitro*** the sense oligoribonucleotide, the antisense oligoribonucleotide or the double stranded RNA comprised thereof as in claim 1. No disclaimer of subject matter is thereby intended. In view of the amendment, the rejection is moot as it applies to a claimed method of inhibiting expression of SBP gene *in vivo*.

The Office further alleges that the enabled subject matter is limited to *in vitro* methods that utilize oligoribonucleotides based on nucleotides 187-205 of SEQ ID NO: 1. Office Action, page 8. The Office notes that the oligoribonucleotides of SEQ ID NOS: 6-7, used in Example 6, differ at one residue from residues 474-494 of SEQ ID NO: 1. Specifically, SEQ ID NO: 6 diverges from the corresponding sequence of SEQ ID NO: 1 as originally filed at position 492, depicted in bold, underline font below:

5'-GAACUUGGAAGAGGGGAG**G**CAdTdT-3' (SEQ ID NO: 6).

The corresponding residue 492 in the target sequence is a C. *See* originally filed SEQ ID NO: 1. The Office alleges that claim 1 accordingly is not enabled for an *in vitro* method comprising the use of oligoribonucleotides that contain bases 474-494 of SEQ ID NO: 1. Office Action, page 6.

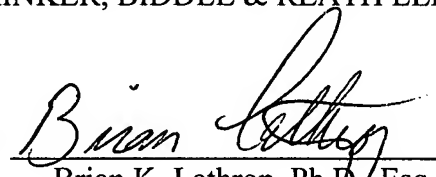
Regardless of a divergence on sequence between SEQ ID NO: 1 and SEQ ID NO: 6, the double stranded oligoribonucleotide of SEQ ID NOS: 6 and 7 nevertheless clearly inhibits the expression of SBP gene in cancer cells, as claimed. *See. e.g.*, Specification, Example 6. As such, Example 6 is a working example of an oligoribonucleotide that targets bases 474-494 of SEQ ID NO: 1, as presently claimed. Accordingly, this aspect of the rejection also may be withdrawn, and the claims should be allowed.

CONCLUSION

In conclusion, this is believed to be in full response to the outstanding restriction requirement. Should any issues remain outstanding or if there are any questions concerning this paper, or the application in general, the Examiner is invited to telephone the undersigned representative at the Examiner's earliest convenience. Should any outstanding fees be owed or overpayments credited, the Commissioner is invited to charge or credit Deposit Account No. 50-0573.

Respectfully submitted,
DRINKER, BIDDLE & REATH LLP

Date: September 13, 2007

By: 

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